



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

Dr. Christine E. Fastnaught
Barley Consultant
National Barley Foods Council
W. 905 Riverside, Suite 501
Spokane, WA 99201

AUG 18 2004

RE: Petition for barley and coronary heart disease health claim (amendment of 21 CFR 101.81)

Dear Dr. Fastnaught:

This letter acknowledges receipt on August 3, 2004, by the Food and Drug Administration (FDA) of your request to modify the petition previously submitted by the National Barley Foods Council on September 25, 2003 pursuant to Section 403(r)(4) of the Federal Food Drug and Cosmetic Act (FFD&C Act)(21 U.S.C. § 343(r)(4)). The petition requests amendment of the regulation that authorizes a health claim relating soluble fiber from certain foods with a decreased risk of coronary heart disease (21 CFR 101.81) to include β -glucan soluble fiber from barley and barley products. With the submission of your modified petition, we establish the receipt of your petition as August 3, 2004.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 100-day period, which ends on November 11, 2004, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

Tomoko Shimakawa, Sc.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2004P-0512

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